K011219

MAY 1 8 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
56 East Bell Drive
Warsaw, IN 46582

Contact: Dalene T. Binkley
Phone: (219) 372-1612

Device(s): Ascent™ Knee System

Classification: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560).

Indications: The indications for the Ascent™ Knee System are for painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved; the correction of varus, valgus, or posttraumatic deformity; and the correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure. The Ascent™ Knee System is for use with bone cement.

Device Description:

Ascent™ 16mm Augments

The Ti-6Al-4V Ascent™ 16mm Augments are intended for use as spacers where excessive distal bone loss exists. The 16mm augment has been added to the series for the option of a thicker spacer that comes in sizes from x-small to xx-large.

Ascent™ 22 and 24mm Posterior Stabilized (PS) and Constrained Bearings

The additional thicker ArCOM® (UHMWPE) bearings are to be used where greater knee joint space needs to be filled. Filling the space will increase the tension of the collateral ligament which will increase the joint stability.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

G0353

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Ms. Dalene T. Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011219
Trade Name: Ascent Knee System
Regulation Number: 21 CFR 888.3560
Regulatory Class: II
Product Code: JWH
Dated: April 19, 2001
Received: April 20, 2001

Dear Ms. Binkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K011219

DEVICE NAME: Ascent™ Knee System

INDICATIONS FOR USE:

The indications for use of the Ascent™ Knee System are for the painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved; the correction of varus, valgus, or posttraumatic deformity; and the correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011219